DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

M3389n

January 28, 2000

WARNING LETTER NYK 2000-28

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John G. Rorer, President
Edelweiss Farms Inc.
10838 Osmun Road
Freedom, New York 14065

Dear Mr. Rorer:

An investigation was conducted at your dairy operation located at 10838 Osmun Road, Freedom, New York; and 7785 Route 19, Gainesville, New York by Investigator Russ E. Davis on November 8, 10, and 15, 1999. The investigation confirmed that you offered animals for sale for slaughter as food in violation of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you have caused animals drugs to become adulterated within the meaning of Section 501(a)(5).

On or about May 24, 1999, you sold a dairy cow identified with ear tag number 21ZCM3733/USDA laboratory report number 270876, at Maplehurst Livestock Market, Inc. USDA analysis of tissue samples from that animal collected May 25, 1999 at the slaughterhouse, Taylor Packing Co., Inc., Wyalusing, Pennsylvania, identified the presence of the drug penicillin at a level of 0.21 ppm in the kidney.

On or about July 28, 1999, you sold a dairy cow identified with farm tag number 937 and ear tag number 21KT4612, sale tag number V 113/USDA laboratory report number 264418, at Empire Livestock Marketing, LLC, Cherry Hill, New York. USDA analysis of tissue samples from that animal collected on July 29, 1999 at the slaughterhouse, Taylor Packing Co., Inc., Wyalusing, Pennsylvania, identified the presence of the drug penicillin at a level of 0.29 ppm in the kidney.

A tolerance of 0.05 ppm has been established for penicillin in the edible tissues of cattle in Title 21 Code of Federal Regulations, Section 556.510. The presence of this drug in edible tissues from these animals causes the foods to be adulterated.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs in edible tissues. Food from animals held under such conditions is adulterated.

You are adulterating the drug Penicillin G Procaine Aqueous Suspension Injectable that your firm uses on dairy cows within the meaning of Section 510(a)(5) when you fail to use the drug in conformance with its approved labeling. Your use of this drug in dairy cows at higher than labeled dosages and without following the labeled withdrawal period causes the drug to be unsafe to use.

You should take prompt action to prevent any subsequent violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action- without further notice. This may include seizure and/or injunction.

It is your responsibility to assure your operations are in compliance with the requirements of the Act. As a diary farmer, you are the individual who introduces or offers for introduction into interstate commerce, the adulterated animal.

You should be aware it is not necessary for you to have personally shipped an animal in interstate commerce or be responsible for a violation of the Act. The fact you offered the animal for sale to an auction barn and/or slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

To reduce the likelihood animals you offer for sale for human food contain illegal drug residues; you should take precautions such as:

1. Develop and maintain medication/treatment records which identify the animal, the date of medication, the drug, the dosage administered, and the required pre-slaughter withdrawal period.

2. Implement a system to assure veterinary drugs such as Penicillin G Procaine are administered in accordance with label instructions.

Please notify this office in writing, within 15 days, of the steps you have taken, or intend to take, to prevent a recurrence of these or similar violations. Your response should be directed to John Thompson, Compliance Officer, at the above address.

Sincerely,

Brenda J. Holman
District Director